

Almirall's Full-Year 2023 Results

Almirall continues its progress to leadership in Medical Dermatology driven by strong growth in the European Dermatology business

- Company revenue growth driven by the strong performance of the European Dermatology business (+17% year-on-year) based on key growth drivers and new launches: Ilumetri[®] growing sales at 33.5% year-on-year; Klisyri[®] strong sales growth of 67% year-on-year; and Wynzora[®] with an outstanding 131% year-on-year sales increase
- Almirall's Net sales reached €894.5 MM (+4% y-o-y) with total EBITDA of €174.1 MM in 2023 (-12.2% y-o-y), mainly due to decreased contributions from other income following last year's AstraZeneca / Covis milestones
- Lebrikizumab (EBGLYSS[®]) obtained EU and UK approval by the end of 2023 for the treatment of patients with moderate-to-severe atopic dermatitis. Positive initial feedback from dermatologists following its successful launch in Germany immediately after approval. Further market rollout is scheduled for 2024 in the UK, Austria, Spain and Denmark, and other countries in 2025
- The late-stage pipeline remains on track: the large field supplementary NDA for Klisyri[®] in the US was submitted in Q3 2023 and is expected to launch in H2 2024; Seysara[®] was submitted in China in Q3 2023
- Today, Almirall announced a licensing agreement of an anti-IL-21 monoclonal antibody with fist-in-class dermatology potential from Novo Nordisk. The company continues to develop its early-stage pipeline with ongoing Phase 1 studies of Anti-IL-1RAP mAb and initiation of Phase I studies of IL-2muFc in December 2023
- Guidance for 2024: Net Sales growth of high single digit and Total EBITDA between €175 MM and €190 MM

Financial highlights (€ rounded million)

	2023	2022	Variation
Total Revenue	898.8	878.5	2.3%
• Net Sales	894.5	863.2	3.6%
• Other Income	4.3	15.3	(71.9%)
Gross Profit	581.4	572.9	1.5%
• % of sales	65%	66.4%	
Total EBITDA	174.1	198.3	(12.2%)
Normalized Net Income	15.6	33.5	(53.4%)
Net Income	(38.5)	4.3	<i>n.m</i>

"2023 was an important year for Almirall, further establishing us as a leader in Dermatology in Europe and showing our significant progress in delivering innovative products to patients that truly impact their lives. An example for our dedication to growing in medical dermatology and our focus on launch excellence is our new biological treatment for moderate to severe atopic dermatitis, EBGLYSS®. Making it available to patients in Germany just a few weeks after approval is testament to our determination to bring innovative and impactful treatments to patients and healthcare professionals. With a compelling benefit profile and a convenient dosing regime, this new biologic represents a significant advancement and is set to transform the treatment paradigm for atopic dermatitis.

We successfully delivered key launches and achieved significant growth in our priority products, such as our psoriasis franchise, and kept growing our existing global dermatology portfolio of around 50 products. Powered by our dedicated investments in launches and innovation, we achieved a 4% year-on-year growth in Net Sales, accounting for €895 MM, which was mainly driven by our European dermatology business. Looking ahead to 2024, we are confident that Almirall's assets and expertise will further drive growth based on the continued support for our key products. For 2024 we anticipate a Net Sales growth of high single-digit and a total EBITDA between €175 MM and €190 MM. We are confident in our ability to further expand our revenue and solidify our position in the dermatology community. We will continue to explore external opportunities for early and mid-stage assets, as well as advancing our exciting early and late-stage pipeline. With our solid balance sheet, and our unwavering dedication to innovation and patient care, we are set up to deliver sustained success and growth in the years to come."

Carlos Gallardo, Almirall's Chairman and CEO.

Almirall, S.A. (ALM) a global biopharmaceutical company based in Barcelona, today announced its full-year 2023 financial results.

Summary of results

- **Net Sales** of €895 MM represented year-on-year growth of 4%, driven by strong performance of the European Dermatology business.
- **In line with expectations, the total EBITDA was** €174 MM, representing a 12% year-on-year reduction. This was mainly driven by investments in the launch of EBGLYSS® and further expansion of Ilumetri, and lower contribution from other income versus FY 2022, specifically from Astra Zeneca / Covis milestones, plus a slightly lower gross margin and higher operating expenses.
- Almirall finished 2023 at 0.2x **Net Debt to EBITDA**, which remains highly favorable despite numerous cash investments, such as the recent Prometax® acquisition, Efficib®/Tesavel® extension deal, Physiorelax® acquisition, Ilumetri® and Klisyri® milestones, and the Isolex upfront payment.
- **Gross Margin** of 65%, as anticipated, was impacted by higher energy costs and inflation affecting purchase costs of certain materials.
- **Research & Development** investment of €111 MM, at 12% of Net Sales 2023.
- **Selling, General & Administrative** expenses were €422 MM, up 3%, due to the support for recent and upcoming launches of Ebglyss®, Wynzora®, Klisyri® in the US and the Ilumetri® rollout in new countries.
- **Normalized Net Income** was €16 MM which differs to Net Income predominantly due to adjusting for the impairment from Seysara®.
- **Net Loss** of €38 MM was due to impairment charges associated with the carrying value of the intangible asset for Seysara®.

Leading medical dermatology in Europe

Significant unmet needs still remain in the dermatology market, which has an estimated annual growth rate of 10% over the next five years, projected to reach €77 billion by 2028*. With a consistent stream of product launches in recent years and robust commercial operations, Almirall has successfully built a strong franchise in dermatology, with a market share of €400 million. The company's commercial efforts extend to covering 60% of office dermatologists and 90% of hospital dermatologists across Europe.

Almirall has become a recognized leader in medical dermatology in Europe thanks to its strong portfolio of more around 50 products in different modalities, predominantly topical, systemic and biologics. Almirall is strategically positioned in the area of immune-mediated inflammatory diseases, including atopic dermatitis and psoriasis, as well as non-melanoma skin cancer, with a strong presence in actinic keratosis, achieving a consistent 17% annual growth rate between 2017 and 2023.

The evolution of Almirall's pipeline makes it increasingly compelling. The company invests considerably in both internal research and development and in-licensing capabilities to achieve sustained pipeline growth, leveraging its highly flexible balance sheet. This sustained financial strength provides a robust foundation for future growth, enabling Almirall to extend its reach within Europe and globally to help people with skin diseases and healthcare professionals.

*Evaluate Pharma data

Biologics

Atopic Dermatitis (AD)

In Q4 2023, the European Commission (EC) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK approved EBGLYSS® (lebrikizumab), an anti-IL13 monoclonal antibody for the treatment of adult and adolescent patients (12 years and older with a body weight of at least 40 kg) with moderate-to-severe atopic dermatitis (AD), who are candidates for systemic therapy. Almirall also **successfully launched the product in Germany** and expects to continue with the market rollout in 2024 focusing on the UK, Austria, Spain, and Denmark. The rollout in remaining European countries is expected in 2025.

According to Evaluate Pharma data, the AD market is in its early stages. The available treatments are still limited for a disease that requires a wide variety of options to provide optimal care for patients. This provides a basis for potentially exponential growth, as was the case for psoriasis in the recent past. **Lebrikizumab has the potential to become a best-in-class treatment for AD** - it represents a significant step forward for patients due to its selective mechanism of action,¹ proven short and long-term efficacy and safety - demonstrated up to 2 years^{2,3,4,5} with a monthly maintenance dosing for all patients.⁶

Almirall anticipates that EBGLYSS® will make an increasing contribution to the performance of its European dermatology business over 2024. Within the psoriasis and atopic dermatitis biologics franchises alone, the company foresees potential peak sales of €700 MM by 2030, fueled by EBGLYSS® and Ilumetri®. With the atopic dermatitis market emerging as the newest field for advanced therapies, it is expected to grow through products with new mechanisms of action, mirroring the trajectory seen in the psoriasis market.

Psoriasis

Ilumetri®, an anti-IL-23 high-affinity humanized monoclonal antibody indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis, delivered solid results across all regions and achieved €166 MM in 2023, a significant year-on-year growth of 33.5%. The balanced performance of the product, with Germany as a key market, shows the strong trajectory of Ilumetri® in key European markets where it has been launched.

Almirall anticipates sustaining this momentum in 2024, with absolute growth expected to be comparable to 2023.

Unlocking the value of the innovative pipeline

Almirall's R&D pipeline is solely focused on medical dermatology, and in 2023 we invested 12,4% of our sales in R&D and will continue to prioritise the progress of our innovative R&D roadmap in the future.

The collaborative mindset within the company has allowed Almirall in 2023 to work closely with leading experts around the globe to innovate and to initiate the development of novel technologies such as AI-based drug discovery, immunology, biological treatments, and mRNA amongst others.

Almirall licenses an anti-IL-21 monoclonal antibody from Novo Nordisk

Today, Almirall announced that it has entered into an exclusive license agreement with Novo Nordisk for rights to the IL-21 blocking monoclonal antibody NN-8828. Under the agreement, Almirall obtains global rights to develop and commercialize this monoclonal antibody in certain fields, including immune inflammatory dermatological diseases. NN-8828 is an IL-21 blocker monoclonal antibody which can inhibit the pathophysiological functions induced by this cytokine in several immune-modulated diseases.

Actinic Keratosis (AK)

Almirall has completed a clinical study addressing the expansion to large field in the US for Klisyri® and submitted a supplementary NDA in August 2023 anticipating a launch in the second half of 2024. Furthermore, in Europe, we have initiated another study to enable this label expansion to large field, expected by 2026.

Autoimmune dermatological diseases

Almirall continues to make progress in its early-stage pipeline, which features a range of promising assets with great value to unlock. The company is currently advancing a phase I study of **ALM27134***, a first-in-class fully human, high-affinity monoclonal antibody that targets IL-1RAP (Interleukin-1 Receptor Accessory Protein) for the treatment of autoimmune dermatological diseases. This monoclonal antibody could bring the opportunity to address the unmet needs in several autoimmune dermatology indications.

Simultaneously, Almirall has initiated Phase I on **ALM223****, an IL-2 mutant fusion protein (IL-2 μ Fc) autoimmune drug candidate developed in collaboration with Simcere. This molecule is designed to activate regulatory T-cells and has the potential to rebalance the immune system in several autoimmune diseases^{7,8}

Acne

The Phase III clinical study of the oral antibiotic Seysara® (sarecycline) in China met primary and key secondary endpoints, and Almirall submitted a dossier to the Chinese National Medical Products Administration at the end of September 2023. Outcome of the review is expected in 2024.

**Previously referred to as ISB 880*

*** ALM223 in licensed from Simcere. Formally referred to as SIM-0278, worldwide ex-Greater China.*

New partnerships for the future development of the pipeline

Almirall has complemented its exciting pipeline and discovery efforts through strategic partnerships, adding long-term value to its medical dermatology portfolio. In Q4, the company announced a drug discovery agreement with Absci, a generative AI drug creation company, to develop and commercialize AI-designed therapeutics to fight chronic and debilitating dermatological diseases. This alliance represents Almirall's first de novo AI drug discovery collaboration and came just months after Absci announced that it could design and validate de novo therapeutic antibodies using its "zero-shot" generative AI.

Additionally, in December, Almirall entered into a multi-target alliance with etherna, an mRNA/LNP technology platform, to discover and develop novel mRNA-based therapies for severe skin diseases, such as non-melanoma skin cancer. This collaboration offers the unique opportunity to use this novel modality to encode multiple therapeutically active compounds in a single treatment.

Conclusions

Almirall met its guidance and further solidified the outstanding performance of its European Dermatology business. The strategic focus on medical dermatology has positioned the company well for sustained growth and leadership in the medium term and beyond.

Throughout 2023, the company achieved significant milestones, including the approval of EBGLYSS® in Europe and the UK and its launch in Germany, alongside continued success with Ilumetri®. Looking ahead, Almirall is committed to maximizing the potential of these biologics, which have peak sales projections of €700 MM and the capacity to transform the company by 2030. Positive momentum from the launches of Klisyri® and Wynzora® in Europe is expected to carry into 2024.

Almirall aims to build upon the positive trajectory of 2023 and unlock further value from its pipeline in 2024. Key milestones include potential approvals for Klisyri® large field in the United States and efinaconazole in Europe, as well as Seysara® in China, bolstering the company's portfolio of innovative products. Additionally, the company continues to advance the studies of its exciting early-stage assets, which are progressing as expected.

The company keeps a long-term view on its contributions and commitment to positively impacting patients, to continue its leadership in dermatology, and to shareholder value creation. Almirall's growth is expected to accelerate in the coming years through recent and upcoming launches. This growth trajectory is complemented by a strategic approach to add valuable assets to Almirall's portfolio by new agreements based on scientific, strategic, and financial considerations.

Investor Calendar 2024

- Q1 2024 Financial Results – 13th May 2024
- H1 2024 Financial Results – 22nd July 2024
- 9M 2024 Financial Results – 11th November 2024

About Almirall

Almirall is a global pharmaceutical company dedicated to medical dermatology. We closely collaborate with leading scientists, healthcare professionals, and patients to deliver our purpose: *to transform the patients' world by helping them realize their hopes and dreams for a healthy life*. We are at the forefront of science to deliver ground-breaking, differentiated medical dermatology innovations that address patients' needs.

Almirall, founded in 1944 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM). Almirall (total revenue in 2023: €898.8 MM, 1900 employees globally) has a direct presence in 21 countries and affiliates in over 70 others.

For more information, please visit almirall.com

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¹ Gonçalves F, et al. Selective IL-13 inhibitors for the treatment of atopic dermatitis. *Drugs Context*. 2021;10:2021-1-7.

² Silverberg JI, Guttman-Yassky E, Thaçi D, et al. Two Phase 3 Trials of Lebrikizumab for Moderate-to-Severe Atopic Dermatitis. *N Engl J Med*. 2023;doi:10.1056/NEJMoa2206714.

³ Simpson EL et al. Efficacy and safety of Lebrikizumab in combination with topical corticosteroids in adolescents and adults with moderate-to-severe atopic dermatitis: a randomized clinical trial (ADhere). *JAMA Dermatol*. Publicado online el 11 de febrero de 2023. doi:10.1001/jamadermatol.2022.5534.

⁴ Blauvelt A, et al. Efficacy and safety of lebrikizumab in moderate-to-severe atopic dermatitis: 52-week results of two randomized double-blinded placebo-controlled phase III trials. *British Journal of Dermatology*. 2023; ljad022, <https://doi.org/10.1093/bjd/ljad022>.

⁵ Guttman-Yassky E, et al. Efficacy and Safety of Lebrikizumab Is Maintained to Two Years in Patients With Moderate-to-Severe Atopic Dermatitis Presented at the Fall Clinical Dermatology Conference; October 20, 2023.

⁶ EBGLYSS (lebrikizumab). EU Summary of Product Characteristics.

⁷ Hernandez R, Pöder J, LaPorte KM, Malek TR. Engineering IL-2 for immunotherapy of autoimmunity and cancer. *Nat Rev Immunol*. 2022 Oct;22(10):614-628. doi: 10.1038/s41577-022-00680-w. Epub 2022 Feb 25. PMID: 35217787.

⁸ Raeber ME, Sahin D, Karakus U, Boyman O. A systematic review of interleukin-2-based immunotherapies in clinical trials for cancer and autoimmune diseases. *EBioMedicine*. 2023 Apr;90:104539. doi: 10.1016/j.ebiom.2023.104539. Epub 2023 Mar 31. PMID: 37004361; PMCID: PMC10111960.